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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,320	02/06/2001	Patrick Page	1103326-0654	3650

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PATENT DEPARTMENT
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NEW YORK, NY 10036

EXAMINER

BAKER, MAURIE GARCIA

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 04/21/2003 //

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/762,320

Applicant(s)

Page

Examiner

Maurie G. Baker

Art Unit

1639



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 5, 2003
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above, claim(s) 6-12 and 14-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6 6) ☐ Other: _____

DETAILED ACTION

1. The Response filed February 5, 2003 (Paper No. 10) is acknowledged. No claims were amended, cancelled or added. Therefore, claims 1-16 are pending.

Election/Restriction

2. Applicant's election with traverse of Group I (claims 1-5 and 13) in Paper No. 10 is acknowledged.

3. With respect to the restriction, applicant argues that the instant claims have unity of invention because the cited technical feature is not known in the art. Applicant argues that the Short reference does not teach a linker that is "cleavable at the CN functionality". First, this phrase is deemed to be indefinite (see rejection under 35 USC 112, second paragraph below). Second, the examiner's position is that the Short reference *does* teach this feature (see art rejection below). Therefore the instant claims are deemed to lack unity of invention. The requirement is still deemed proper and is therefore made FINAL.

4. Claims 6-12 and 14-16 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 10.

5. Therefore, claims 1-5 and 13 are examined on the merits in this action.

Specification

6. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1 and 13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. Applicant's claims are directed to a "functionalized polymeric reagent" comprising "a polymer and a linker moiety" where the linker moiety "comprises an acid labile isonitrile moiety". There are a virtually unlimited number of compounds that would fall within the claimed genus of "polymer" and linker moiety comprising "an acid labile isonitrile moiety". The instant specification discloses only limited examples of the claimed

reagents. This disclosure is neither representative of the claimed genus, nor does it represent a substantial portion of the claimed genus.

Note that the language of the specification should describe the claimed invention so that one skilled in the art can recognize what is claimed. A description of a compound in terms of its function fails to distinguish the compound from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. *University of California v. Eli Lilly and Co.* (U.S. Court of Appeals Federal Circuit (CAFC) 43 USPQ2d 1398 7/22/1997 Decided July 22, 1997; No. 96-1175).

With respect to adequate disclosure of the scope of the presently claimed generic applicant is referred to the discussion in *University of California v. Eli Lilly and Co.* (cited above) regarding disclosure. For adequate disclosure, like enablement, requires representative examples which provide reasonable assurance to one skilled in the art that the compounds falling within the scope both possess the alleged utility and additionally demonstrate that applicant had possession of the full scope of the claimed invention. See *In re Riat* (CCPA 1964) 327 F2d 685, 140 USPQ 471; *In re Barr* (CCPA 1971) 444 F 2d 349, 151 USPQ 724 (for enablement) and *University of California v. Eli Lilly and Co.* cited above (for disclosure). The more unpredictable the art the greater the showing required (e.g. by “representative examples”) for both enablement and adequate disclosure.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-5 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claim 1 (and all claims dependent thereon) recites “an acid labile isonitrile moiety” that is “cleavable at the CN functionality”. First, “acid labile” is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear how acid labile the moiety must be to meet the limitations of the claim. Second, “cleavable at the CN functionality” is simply confusing. The claimed invention is a “reagent” with an isonitrile “linker”. Thus apparently the CN functionality would link the reagent to another moiety. After linkage, there is no longer a CN moiety, it has now been functionalized (e.g. to an amine) --- see instant specification page 21 for an example of this concept. The functionalization must occur for there to be anything to be cleaved. Thus, “cleavable at the CN functionality” has no meaning.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Short et al (Tet. Letters, 1997; of record).

As stated above, “cleavable at the CN functionality” is confusing. The claimed invention is a “reagent” with an isonitrile “linker”. Thus apparently the CN functionality would link the reagent to another moiety. After linkage, there is no longer a CN moiety, it has now been functionalized (e.g. to an amine) --- see instant specification page 21 for an example of this concept. The functionalization must occur for there to be anything to be cleaved. Thus, “cleavable at the CN functionality” has no meaning. For the purposes of this rejection, “cleavable at the CN functionality” is interpreted to mean that a moiety is cleaved at the position where the CN functionality was previously present (i.e. from where it was linked).

Short et al disclose a polymer supported isocyanide (isonitrile) reading on claim 1 (see Scheme 3 of the reference). Specifically, this polymeric reagent is an isocyanide (reading on the claimed “acid labile isonitrile moiety”) bound to a Wang resin (reading on the claimed polymer). The polymer bound compounds of

Short et al are reacted with ω -ketoacids, and then ultimately cleaved from the resin with TFA (trifluoroacetic acid), which meets the "acid-labile" requirement of the claim (see Short et al, page 360). Moreover, the polymer supported isocyanides of Short et al are used in a method of solid-phase synthesis. See Scheme 3 of the reference where the reaction and then further cleavage from the resin is disclosed. As the compounds are specifically shown in Scheme 3 to be cleaved from the position where the CN functionality was previously present (i.e. from where it was linked), the reference anticipates the claims.

Status of Claims/Conclusion

13. No claims are allowed.
14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie Garcia Baker, Ph.D. whose telephone number is (703) 308-0065. The examiner is on an increased flextime schedule but can normally be reached on Monday-Thursday and alternate Fridays from 9:30 to 7:00.
15. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang, can be reached at (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding

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should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie Garcia Baker, Ph.D.
April 17, 2003



MAURIE GARCIA BAKER PH.D.
PRIMARY EXAMINER